

## Complete Summary

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### GUIDELINE TITLE

Gastroscopy following a positive fecal occult blood test and negative colonoscopy: guideline recommendations.

### BIBLIOGRAPHIC SOURCE(S)

Allard J, Cosby R, Del Giudice ME, Irvine EJ, Morgan D, Tinmouth J. Gastroscopy following a positive fecal occult blood test and negative colonoscopy: guideline recommendations. Toronto (ON): Cancer Care Ontario (CCO); 2009 Mar 30. 29 p. (Evidence-based series; no. 15-6). [34 references]

### GUIDELINE STATUS

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the [Cancer Care Ontario Web site](#) for details on any new evidence that has emerged and implications to the guidelines.

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## SCOPE

### DISEASE/CONDITION(S)

- Positive fecal occult blood test (FOBT)
- Colorectal cancer

### GUIDELINE CATEGORY

Screening  
Technology Assessment

### **CLINICAL SPECIALTY**

Family Practice  
Gastroenterology  
Internal Medicine  
Oncology  
Surgery

### **INTENDED USERS**

Advanced Practice Nurses  
Nurses  
Physician Assistants  
Physicians

### **GUIDELINE OBJECTIVE(S)**

To evaluate if gastroscopy for upper gastrointestinal (UGI) cancer should be performed for patients with a positive fecal occult blood test (FOBT) and negative colonoscopy who are participating in a population-based colorectal cancer (CRC) screening program

### **TARGET POPULATION**

Men and women who participate in a colorectal cancer (CRC) screening program and have had a positive fecal occult blood test (FOBT) followed by colonoscopy without identifiable colonic lesions to account for their positive FOBT

### **INTERVENTIONS AND PRACTICES CONSIDERED**

Esophagogastroduodenoscopy

### **MAJOR OUTCOMES CONSIDERED**

Detection of gastric or esophageal cancer

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases  
Searches of Unpublished Data

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

## **Literature Search Strategy**

The MEDLINE (1990 through May [week one] 2008) and EMBASE (1990 through week 20 2008) databases were searched for relevant publications, using search terms pertaining to colonoscopy, gastroscopy, and gastrointestinal neoplasms. Several key papers were indexed using very different terms, and therefore the search strategies were modified and repeated in an effort to capture the relevant literature. The full MEDLINE and EMBASE literature search strategies can be found in Appendices 2 and 3 in the original guideline document, respectively. The starting date of the search was 1990 as this is when evidence regarding screening began to appear in the literature.

## **Environmental Scan**

An environmental scan was conducted in May 2008 to locate published and unpublished documents outside the indexed literature. Documents pertaining to upper gastrointestinal (UGI) screening for those patients who are colonoscopy negative following a positive fecal occult blood test (FOBT) in a population-based colorectal cancer (CRC) screening program from Canada and health care organizations in the United States of America (USA), United Kingdom (UK), Australia, and New Zealand were searched. For a complete list of websites searched, please refer to Appendix 4 in the original guideline document.

## **Study Selection Criteria**

### *Inclusion Criteria*

Articles were selected for inclusion in the systematic review if they were published English-language reports involving human participants, including practice guidelines, systematic reviews (with or without meta-analyses), and all publication types, except those listed in the exclusion criteria, that examined the role of UGI screening in patients who had a negative colonoscopy following a positive FOBT.

If an esophagogastroduodenoscopy (EGD) was not performed after a negative colonoscopy and patients were followed to determine a new occurrence of UGI cancer, the studies involved were included only if they reported cases of UGI cancers occurring within three years of the positive FOBT. Three years was chosen based on the mean sojourn time for CRC (the time between an undetectable preclinical screening and the clinical phase) that has been reported to be 2.8 years in a Taiwanese study and 2.6 years in a French study.

In theory, population screening should include only asymptomatic participants, but in practice, some people presenting for screening will be symptomatic, which realistically reflects medical practice. For this reason, papers dealing with either symptomatic or asymptomatic patients were retained. At a minimum, a group of FOBT-positive/colonoscopy-negative patients had to be identified in the paper.

### *Exclusion Criteria*

Letters, editorials, notes, case-reports, commentaries, and non-systematic reviews were not included in the systematic review.

## **NUMBER OF SOURCE DOCUMENTS**

The MEDLINE search yielded 439 hits, 36 of which were potentially relevant and ordered for full review; five met selection criteria and were retained. The EMBASE search yielded 1119 hits, of which 34 were potentially relevant, excluding duplicates from the MEDLINE search; three met selection criteria and were retained. A search of the reference lists of included studies yielded 14 hits, of which one was retained.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus (Committee)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

There was considerable heterogeneity in the design methodology of the studies selected and outcomes reported; this, together with a lack of fully published randomized controlled trials (RCTs), did not support pooling data using meta-analytic techniques.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

This evidence-based series (EBS) was developed by the Upper Gastrointestinal (GI) Screening Panel of the Cancer Care Ontario Program in Evidence-Based Care (CCO PEBC). The series is a convenient and up-to-date source of the best available evidence on gastroscopy screening following a positive fecal occult blood test (FOBT) and negative colonoscopy, developed through a review of the evidentiary base, evidence synthesis, and input from external review participants by the Panel. The Panel consisted of gastroenterologists, a family physician, a methodologist, and a CCO representative (see Appendix 1 of Section 2 of the original guideline document for a complete list).

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

### **Report Approval Panel**

Prior to the submission of this evidence-based series (EBS) draft report for external review, the report was reviewed and approved by the Program in Evidence-based Care (PEBC) Report Approval Panel (RAP), which consists of two members, including an oncologist, with expertise in clinical and methodology issues. Key issues raised by the RAP and their resolution by the Upper Gastrointestinal (GI) Screening Panel are summarized in the original guideline document.

### **Expert Panel**

Prior to the submission of this EBS draft report for external review, the report was reviewed by an Expert Panel which consisted of a group of endoscopists from the Clinical Advisory Committee of Cancer Care Ontario's Colorectal Cancer Screening Program. Key issues raised by the Expert Panel, not already covered in the RAP comments, and their resolution by the Upper GI Screening Panel are summarized in the original guideline document.

### **External Review by Ontario Clinicians**

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following the review and discussion of [Section 1: Recommendations](#) and [Section 2: Evidentiary Base](#) in the original guideline document of this EBS and review and approval of the report by the PEBC Report Approval Panel, the Upper GI Screening Panel circulated Sections 1 and 2 to external review participants for review and feedback.

## **Methods**

*Targeted Peer Review:* During the guideline development process, six targeted peer reviewers from Ontario, Nova Scotia, Quebec, and Alberta considered to be

clinical and/or methodological experts on the topic were identified by Upper GI Screening Panel. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Four reviewers agreed, and the draft report and a questionnaire were sent via email or mail for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on January 30, 2009. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The Upper GI Screening Panel reviewed the results of the survey.

*Professional Consultation:* Feedback was obtained through a brief online survey of health care professionals who are the intended users of the guideline, namely gastroenterologists, family physicians, and surgeons. Participants were asked to rate the overall quality of the guideline (Section 1) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1) and the evidentiary base (Section 2). The notification email was sent on February 4, 2009. The consultation period ended on February 28, 2009. The Upper GI Screening Panel reviewed the results of the survey.

This EBS report reflects the integration of feedback obtained through the external review process with final approval given by the Upper GI Screening Panel and the Report Approval Panel of the PEBC.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The current body of evidence is insufficient to recommend for or against, in a population-based colorectal cancer (CRC) screening program, routine esophagogastroduodenoscopy (EGD) in fecal occult blood test (FOBT) positive/colonoscopy negative patients to detect gastric or esophageal cancers. The decision to undertake an EGD should be based on clinical judgement and should be individualized.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by prospective and retrospective studies.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Four prospective and five retrospective studies of patients who were fecal occult blood test (FOBT) positive/colonoscopy negative and had an esophagogastroduodenoscopy (EGD). Of these, two studies reported positive EGD but no information about endoscopic findings and several studies did not document the presence of anemia, upper gastrointestinal (UGI) symptoms or use of non steroidal anti-inflammatory drugs (NSAIDS).
- Based on this limited evidence, EGD had a low yield for UGI cancer, generally  $\leq 1\%$ , even in symptomatic or severely anemic patients. The yield for detecting non-malignant findings potentially contributing to positive FOBT was 11-21% while the yield for incidental findings unlikely contributing to positive FOBT was 10-36%. There were very few data regarding EGD results in the context of anemia or NSAIDS use.

### POTENTIAL HARMS

Esophageal perforation may be a complication of esophagogastroduodenoscopy.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- A recommendation regarding the use of esophagogastroduodenoscopy (EGD) for the detection of non-cancerous pathology is not provided because it is beyond the scope of this review.
- Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

## **IOM DOMAIN**

Effectiveness

### **IDENTIFYING INFORMATION AND AVAILABILITY**

#### **BIBLIOGRAPHIC SOURCE(S)**

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#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2009 Mar 30

#### **GUIDELINE DEVELOPER(S)**

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

#### **GUIDELINE DEVELOPER COMMENT**

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

#### **SOURCE(S) OF FUNDING**

Cancer Care Ontario  
Ontario Ministry of Health and Long-Term Care

#### **GUIDELINE COMMITTEE**

Upper GI Screening Working Panel

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Panel Members:* Johane Allard, *Chair*, Gastroenterologist; Roxanne Cosby, Methodologist; M.E (Lisa) Del Giudice, Family Physician; E. Jan Irvine, Gastroenterologist; Nancy Lewis CCO, Representative, Screening Program; David Morgan, Gastroenterologist; Jill Tinmouth, Gastroenterologist

#### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

All authors report no conflicts of interest.

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [Cancer Care Ontario Web site](#).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI Institute on September 24, 2009.

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